11-8-06 IFW 1646

Attorney Docket: 200512.00047

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Edward M. Medof and Lisa Kuttner-Kondo

Filed: 21 July 2006 **Examiner:** Not yet assigned

Serial No: 10/597,373 **Art Unit:** 1646

For: HYBRID AND CHIMERIC POLYPEPTIDES THAT REGULATE ACTIVATION OF COMPLEMENT

Date: 7 November 2006

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Transmitted herewith:

1) Information Disclosure Statement
2) PTO/SB/08a Form
3) Twentyseven (27) non patent literature documents
4) Acknowledgement of Receipt/Return Card

HAHN LOESER + PARKS LLP

By _____
John J. Cunniff
Reg. No. 42,451

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Filed:	21 July 2006	**Examiner:**	Not yet assigned
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Under 37 CFR §1.97

This Information Disclosure Statement is filed within three months of filing or before a first Office Action on the merits, and therefore, it is timely filed without payment of a fee. 37 CFR §1.97(b).

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR §1.56(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

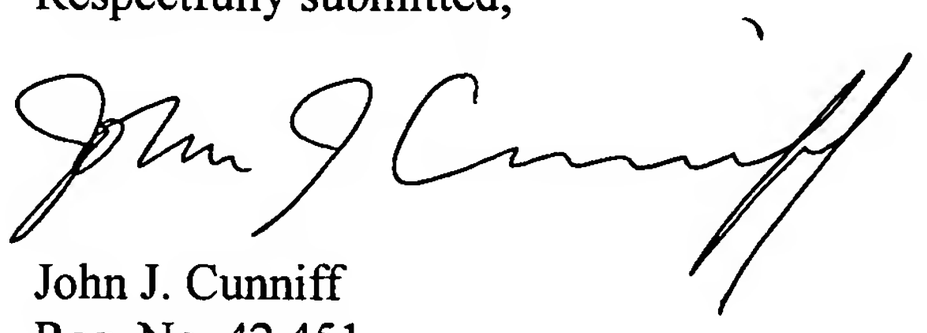
The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13, at 25.

This Information Disclosure Statement is made to comply with the duty of candor imposed on all individuals associated with the filing or prosecution of this application, as defined by 37 CFR §1.56(c).

Twentyseven (27) non patent literature documents are listed on the attached six (6) sheets of Form PTO/SB/08A which is made a part hereof. A copy of each of the non patent literature documents are enclosed.

The foregoing Information Disclosure Statement is based upon the information known to the inventor or contained in the undersigned attorney's file as of the filing date of this statement and is inclusive of the best information known to each of the undersigned at that date. Prompt consideration of the Information Disclosure Statement and the references by the Examiner is earnestly requested.

Respectfully submitted,



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Approved for use through 07/31/2006. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10597373
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Examiner Name	
Attorney Docket Number	200512.00047

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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U.S.PATENT APPLICATION PUBLICATIONS

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FOREIGN PATENT DOCUMENTS

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	1	KUTTNER-KONDO and MEDOF; "Engineering of DAF-CR1 and DAF-MCP hybrid proteins for enhanced function;" Abstracts/Molecular Immunology; 2004; pgs. 264-265 (Abstract #138); Vol. 41	☐
	2	WEISMAN et al.; "Soluble human complement receptor type 1: in vivo inhibitor of complement suppressing post-ischemic myocardial inflammation and necrosis;" Science; July 13, 1990; pgs. 146-151; Vol. 249	☐
	3	KALLI et al.; "Mapping of the C3b-binding site of CR1 and construction of a (CR1)2-F(ab')2 chimeric complement inhibitor;" J. Exp. Med.; December 1991; pgs. 1451-1460; Vol. 174; The Rockefeller University Press	☐
	4	SONG et al.; "Complement receptor 2-mediated targeting of complement inhibitors to sites of complement activation;" The Journal of Clinical Investigation; June 2003; pgs. 1875-1885; Vol. 111, No. 12	☐
	5	FODOR et al.; "A novel bifunctional chimeric complement inhibitor that regulates C3 convertase and formation of the membrane attack complex;" The Journal of Immunology; 1995; pgs. 4135-4138; Vol. 155; The American Association of Immunologists	☐
	6	HIGGINS et al.; "A soluble chimeric complement inhibitory protein that possesses both decay-accelerating and factor I cofactor activities;" The Journal of Immunology; 1997; pgs. 2872-2881; Vol. 158; The American Association of Immunologists; U.S.A.	☐
	7	SALERNO et al.; "A soluble chimeric inhibitor of C3 and C5 convertases, complement activation blocker-2, prolongs graft survival in pig-to-rhesus monkey heart transplantation;" Xenotransplantation; 2002; pgs. 125-134; Vol. 9; United Kingdom	☐
	8	KROSHUS et al.; "A recombinant soluble chimeric complement inhibitor composed of human CD46 and CD55 reduces acute cardiac tissue injury in models of pig-to-human heart transplantation;" Transplantation; June 15, 2000; pgs. 2282-2289; Vol. 69, No. 11; Lippincott Williams & Wilkins, Inc.; U.S.A.	☐
	9	LI et al.; "Pharmacokinetics and safety of TP10, soluble complement receptor 1, in infants undergoing cardiopulmonary bypass;" American Heart Journal; January 2004; pgs. 173-180; Vol. 147; Elsevier Inc., U.S.A.	☐
	10	LAZAR et al.;"Soluble human complement receptor 1 limits ischemic damage in cardiac surgery patients at high risk requiring cardiopulmonary bypass;" Circulation; September 14, 2004; pgs. II274-II279; Issue No. 0009-7322; Vol. 110 (Suppl II); The American Heart Association; Dallas, TX U.S.A.	☐
	11	SCHMID et al.; "TP20 is superior to TP10 in reducing ischemia/reperfusion injury in rat lung grafts;" Transplantation Proceedings; 2001; pgs. 948-949; Vol. 33; Elsevier Science Inc.; New York, NY U.S.A.	☐

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	12	ZIMMERMAN et al.; "Phase I trial of the recombinant soluble complement receptor 1 in acute lung injury and acute respiratory distress syndrome;" Crit Care Med; 2000; pgs. 3149-3154; Vol. 28, No. 9; Lippincott Williams & Wilkins; U.S.A.	☐
	13	COUSER et al.; "The effects of soluble recombinant complement receptor 1 on complement-mediated experimental glomerulonephritis;" Journal of the American Society of Nephrology; 1995; pgs. 1888-1894; Vol. 5, No. 11; The American Society of Nephrology; U.S.A.	☐
	14	KRYCH-GOLDBERG et al.; "Synergy between two active sites of human complement receptor type 1 (CD35) in complement regulation: implications for the structure of the classical pathway C3 convertase and generation of more potent inhibitors;" Journal of Immunology; 2005; pgs. 4528-4535; Vol. 175; The American Association of Immunologists, Inc. U.S.A.	☐
	15	HARRIS et al.; "Coupling complement regulators to immunoglobulin domains generates effective anti-complement reagents with extended half-life in vivo;" Clinical and Experimental Immunology; 2002; pgs. 198-207; Vol. 129; Blackwell Science	☐
	16	HARRIS et al.; "Generation of anti-complement "prodrugs": cleavable reagents for specific delivery of complement regulators to disease sites;" Journal of Biological Chemistry; September 19, 2003; pgs. 36068-36076; Vol. 278, No. 38; The American Society for Biochemistry and Molecular Biology, Inc.; U.S.A.	☐
	17	IWATA et al.; "Expression of a hybrid complement regulatory protein, membrane cofactor protein decay accelerating factor on Chinese Hamster Ovary. Comparison of its regulatory effect with those of decay accelerating factor and membrane cofactor protein;" Journal of Immunology; 1994; pgs. 3436-3444; Vol. 152; The American Association of Immunologists; U.S.A.	☐
	18	CHRISTIANSEN et al.; "Engineering of recombinant soluble CD46: an inhibitor of complement activation;" Immunology; 1996; pgs. 348-354; Vol. 87; Blackwell Science Ltd.	☐
	19	RINDER et al.; "Role of C3 cleavage in monocyte activation during extracorporeal circulation;" Circulation; August 3, 1999; pgs. 553-558; Vol. 100; American Heart Association, Inc.; Dallas, TX U.S.A.	☐
	20	SOUZA et al; "APT070 (Mirococept), a membrane-localised complement inhibitor, inhibits inflammatory responses that follow intestinal ischaemia and reperfusion injury;" British Journal of Pharmacology; 2005; pgs. 1027-1034; Vol. 145; Nature Publishing Group	☐
	21	LAM et al.; "The effect of soluble complement receptor type 1 on acute humoral xenograft rejection in hDAF-transgenic pig-to-primate life-supporting kidney xenografts;" Xenotransplantation; 2005; pgs. 20-29; Vol. 12; Singapore	☐
	22	HENRY et al.; "Complement activation is responsible for acute toxicities in rhesus monkeys treated with a phosphorothioate oligodeoxynucleotide;" International Immunopharmacology; 2002, pgs. 1657-1666; Elsevier Science B.V.	☐

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	23	VON DOBSCHUETZ et al.; "Soluble complement receptor 1 preserves endothelial barrier function and microcirculation in postischemic pancreatitis in the rat;" American Journal of Physiology - Gastrointestinal Liver Physiology; December 23, 2003; pgs. 791-796; Vol. 286; American Physiological Society; Bethesda, MD U.S.A.	☐
	24	YAZDANBAKHSH, KARINA; "Development of complement therapeutics for inhibition of immune-mediated red cell destruction;" Transfusion; August 2005; pgs. 122S-129S; Vol. 45	☐
	25	XOMA Ltd.; "MLN01 and CAB-2 with Millennium Pharmaceuticals, Inc.;" Press Release; May 15, 2003; pg. 2; U.S.A.	☐
	26	BIOSPACE BEAT; "XOMA (XOMA) and Millennium Pharmaceuticals, Inc. (California) (MLNM) announce initiation of phase I clinical trial of MLN2222 – A.K.A. CAB-2 – a novel complement inhibitor;" Press Release; December 18, 2003; U.S.A.	☐
	27	AVANT IMMUNOTHERAPEUTICS, INC.; www.avantimmune.com/products/tp10.html and www.avantimmune.com/products/tp20.html	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

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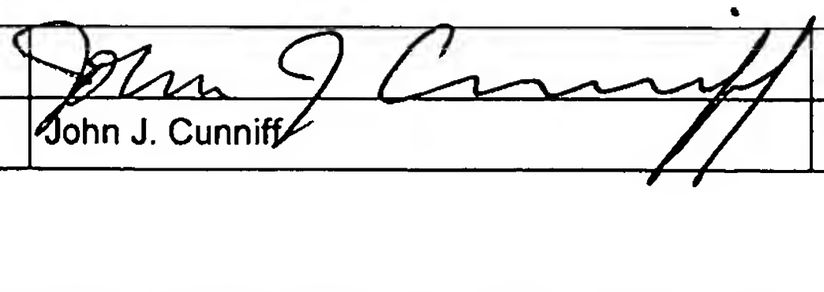
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-11-06
Name/Print	John J. Cunniff	Registration Number	42451

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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